


1 Identification

- **Product identifier**
- **Trade name:** Formaldehydi Kutvirtti gargarisma
- **Article number:** 610773
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutical preparations
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Inc
2400 Pilot Knob Road
St. Paul, MN 55120
www.fagron.us
QA@fagron.us
- **Information department:**
Tel.: 800-423-6967
Fax: 800-339-1596
- **Emergency telephone number:**
Emergency Telephone:
US: 1-800-535-5053
International: 1-352-323-3500

2 Hazard(s) identification

- **Classification of the substance or mixture**
Flammable Liquids 2 H225 Highly flammable liquid and vapor.
Sensitization - Skin 1 H317 May cause an allergic skin reaction.
Germ Cell Mutagenicity 2 H341 Suspected of causing genetic defects.
Carcinogenicity 1A H350 May cause cancer.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

GHS02 GHS07 GHS08
- **Signal word** Danger
- **Hazard-determining components of labeling:**
Ethanol / Alcohol 99,5% v/v (absolute formaldehyde)
- **Hazard statements**
Highly flammable liquid and vapor.
May cause an allergic skin reaction.
Suspected of causing genetic defects.
May cause cancer.
- **Precautionary statements**
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.

(Contd. on page 2)

USA

Safety Data Sheet

acc. to OSHA HCS

Page 2/11

Printing date 04/09/2024

Reviewed on 04/09/2024

Trade name: Formaldehydi Kutvirtti gargarisma

(Contd. of page 1)

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Keep container tightly closed.
Ground/bond container and receiving equipment.
Use explosion-proof electrical/ventilating/lighting/equipment.
Use only non-sparking tools.
Take precautionary measures against static discharge.
Avoid breathing dust/fume/gas/mist/vapors/spray
Contaminated work clothing must not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
If exposed or concerned: Get medical advice/attention.
Specific treatment (see on this label).
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.
In case of fire: Use CO₂, powder or water spray to extinguish.
Store in a well-ventilated place. Keep cool.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMS-ratings (scale 0 - 4)**



· **Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	50–≤100%
CAS: 50-00-0	formaldehyde	≥3–<5%
CAS: 2216-51-5	L-menthol	1–≤3%

4 First-aid measures

· **Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.
In case of irregular breathing or respiratory arrest provide artificial respiration.

(Contd. on page 3)

USA

Trade name: Formaldehydi Kutvirtti gargarisma

(Contd. of page 2)

Remove breathing apparatus only after contaminated clothing have been completely removed.

• **After inhalation:**

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

• **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

• **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

• **After swallowing:**

Seek immediate medical advice.

Call a doctor immediately.

• **Information for doctor:**

• **Most important symptoms and effects, both acute and delayed**

No further relevant information available.

• **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Fire-fighting measures

• **Extinguishing media**

• **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

• **Special hazards arising from the substance or mixture**

Formation of toxic gases is possible during heating or in case of fire.

• **Advice for firefighters**

• **Protective equipment:**

Wear self-contained respiratory protective device.

Wear fully protective suit.

6 Accidental release measures

• **Personal precautions, protective equipment and emergency procedures**

Mount respiratory protective device.

Wear protective equipment. Keep unprotected persons away.

• **Environmental precautions:**

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

• **Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to section 13.

Dispose of the collected material according to regulations.

Ensure adequate ventilation.

• **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

• **Protective Action Criteria for Chemicals**

• **PAC-1:**

CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute)

1,800 ppm

(Contd. on page 4)

USA

Safety Data Sheet

acc. to OSHA HCS

Page 4/11

Printing date 04/09/2024
Reviewed on 04/09/2024

Trade name: Formaldehydi Kutvirtti gargarisma

(Contd. of page 3)

CAS: 50-00-0	formaldehyde	0.90 ppm
CAS: 67-56-1	methanol	530 ppm
· PAC-2:		
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	3300* ppm
CAS: 50-00-0	formaldehyde	14 ppm
CAS: 67-56-1	methanol	2,100 ppm
· PAC-3:		
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	15000* ppm
CAS: 50-00-0	formaldehyde	56 ppm
CAS: 67-56-1	methanol	7200* ppm

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**

· Components with limit values that require monitoring at the workplace:

CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute)

PEL	Long-term value: 1900 mg/m ³ , 1000 ppm
REL	Long-term value: 1900 mg/m ³ , 1000 ppm
TLV	Short-term value: 1000 ppm
A3	

CAS: 50-00-0 formaldehyde

PEL	Short-term value: 2 ppm Long-term value: 0.75 ppm see 29 CFR 1910.1048(c)
-----	---

(Contd. on page 5)

USA

Safety Data Sheet

acc. to OSHA HCS

Page 5/11

Printing date 04/09/2024
Reviewed on 04/09/2024

Trade name: Formaldehydi Kutvirtti gargarisma

(Contd. of page 4)

REL	Long-term value: 0.016 ppm Ceiling limit value: 0.1* ppm *15-min; See Pocket Guide App. A
TLV	Short-term value: 0.3 ppm Long-term value: 0.1 ppm DSEN; RSEN, A1
CAS: 2216-51-5 L-menthol	
WEEL	Short-term value: 19.2* mg/m ³ , 3* ppm Long-term value: 6.4* mg/m ³ , 1* ppm *OARS WEEL

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
 - Keep away from foodstuffs, beverages and feed.
 - Immediately remove all soiled and contaminated clothing.
 - Wash hands before breaks and at the end of work.
 - Store protective clothing separately.
 - Avoid contact with the eyes and skin.
 - Pregnant women should strictly avoid inhalation or skin contact.
 - Do not eat, drink, smoke or sniff while working.
 - Clean skin thoroughly immediately after handling the product.
 - Do not inhale gases / fumes / aerosols.
- **Breathing equipment:**
 - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 6)

USA

Trade name: Formaldehydi Kutvirtti gargarisma

(Contd. of page 5)

· Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Liquid
Color:	Red-brown
· Odor:	Characteristic
· Odor threshold:	Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	78°C (172.4°F)

· Flash point: 13°C (55.4°F)

· Flammability (solid, gaseous): Flammable.
Highly flammable.

· Auto igniting: 425°C (797°F)

· Decomposition temperature: Not determined.

· Ignition temperature: Product is not selfigniting.

· Danger of explosion: Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

· Explosion limits:

Lower:	3.5 Vol %
Upper:	15 Vol %

· Vapor pressure at 20°C (68°F): 59 hPa (44.3 mm Hg)

· Vapor pressure at 50°C (122°F): 280 hPa (210 mm Hg)

· Density at 20°C (68°F): 0.87434–0.87483 g/cm³ (7.29637–7.30046 lbs/gal)

· Bulk density:	866–871 kg/m ³
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.

· Solubility in / Miscibility with Water: Fully miscible.

· Partition coefficient (n-octanol/water): Not determined.

(Contd. on page 7)

USA

Safety Data Sheet

acc. to OSHA HCS

Page 7/11

Printing date 04/09/2024
Reviewed on 04/09/2024

Trade name: Formaldehydi Kutvirtti gargarisma

(Contd. of page 6)

· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	57.5–57.7 %
Water:	38.3 %
VOC content:	57.52–57.72 % 504.6–504.9 g/l / 4.21 lb/gal
Solids content:	2.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

ATE (Acute Toxicity Estimate)

Oral	LD50	>5731 mg/kg (rat)
Dermal	LD50	8597 mg/kg
Inhalative	LC50/4 h	86 mg/l

CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute)

Oral	LD50	7060 mg/kg (rat)
Inhalative	LC50/4 h	51 mg/l (rat)

CAS: 50-00-0 formaldehyde

Oral	LD50	>200 mg/kg (rat)
------	------	------------------

CAS: 2216-51-5 L-menthol

Oral	LD50	3300 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rabbit)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.

(Contd. on page 8)

USA

Trade name: Formaldehydi Kutvirtti gargarisma

(Contd. of page 7)

· **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	1
CAS: 50-00-0	formaldehyde	1

· **NTP (National Toxicology Program)**

CAS: 50-00-0	formaldehyde	K
--------------	--------------	---

· **OSHA-Ca (Occupational Safety & Health Administration)**

CAS: 50-00-0	formaldehyde	
--------------	--------------	--

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Water hazard class 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· **UN-Number**

· **DOT, IMDG, IATA**

UN1993

(Contd. on page 9)



USA

Safety Data Sheet

acc. to OSHA HCS

Trade name: Formaldehydi Kutvirtti gargarisma

(Contd. of page 8)

<ul style="list-style-type: none"> · UN proper shipping name · DOT · IMDG · IATA 	<p>Flammable liquids, n.o.s. (Ethanol) FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL)) Flammable liquid, n.o.s. (ETHANOL)</p>
<ul style="list-style-type: none"> · Transport hazard class(es) · DOT 	
<ul style="list-style-type: none"> · Class · Label 	<p>3 Flammable liquids 3</p>
<ul style="list-style-type: none"> · IMDG, IATA 	
<ul style="list-style-type: none"> · Class · Label 	<p>3 Flammable liquids 3</p>
<ul style="list-style-type: none"> · Packing group · DOT, IMDG, IATA 	<p>II</p>
<ul style="list-style-type: none"> · Environmental hazards: 	<p>Not applicable.</p>
<ul style="list-style-type: none"> · Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category 	<p>Warning: Flammable liquids 33 F-E, S-E B</p>
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code 	<p>Not applicable.</p>
<ul style="list-style-type: none"> · Transport/Additional information: · DOT · Quantity limitations 	<p>On passenger aircraft/rail: 5 L On cargo aircraft only: 60 L</p>
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml</p>
<ul style="list-style-type: none"> · UN "Model Regulation": 	<p>UN 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL)), 3, II</p>

USA

(Contd. on page 10)

Trade name: Formaldehydi Kutvirtti gargarisma

(Contd. of page 9)

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- Sara

• Section 355 (extremely hazardous substances):

CAS: 50-00-0	formaldehyde
--------------	--------------

• Section 313 (Specific toxic chemical listings):

CAS: 50-00-0	formaldehyde
--------------	--------------

CAS: 67-56-1	methanol
--------------	----------

• TSCA (Toxic Substances Control Act):

CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	ACTIVE
--------------	--	--------

CAS: 7732-18-5	Water, distilled, conductivity or of similar purity	ACTIVE
----------------	---	--------

CAS: 50-00-0	formaldehyde	ACTIVE
--------------	--------------	--------

CAS: 2216-51-5	L-menthol	ACTIVE
----------------	-----------	--------

CAS: 67-56-1	methanol	ACTIVE
--------------	----------	--------

• Hazardous Air Pollutants

CAS: 50-00-0	formaldehyde
--------------	--------------

CAS: 67-56-1	methanol
--------------	----------

• Proposition 65

• Chemicals known to cause cancer:

CAS: 50-00-0	formaldehyde
--------------	--------------

• Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

• Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

• Chemicals known to cause developmental toxicity:

CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)
--------------	--

CAS: 67-56-1	methanol
--------------	----------

• Carcinogenic categories

• EPA (Environmental Protection Agency)

CAS: 50-00-0	formaldehyde	B1
--------------	--------------	----

• TLV (Threshold Limit Value)

CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	A3
--------------	--	----

CAS: 50-00-0	formaldehyde	A2
--------------	--------------	----

• NIOSH-Ca (National Institute for Occupational Safety and Health)

CAS: 50-00-0	formaldehyde
--------------	--------------

• National regulations:

• Information about limitation of use:

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.

- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

Trade name: Formaldehydi Kutvirtti gargarisma

(Contd. of page 10)

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:**

Fagron US
Quality Assurance

- **Contact:** QA@fagron.us

- **Date of preparation / last revision** 04/09/2024

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flammable Liquids 2: Flammable liquids – Category 2

Sensitization - Skin 1: Skin sensitisation – Category 1

Germ Cell Mutagenicity 2: Germ cell mutagenicity – Category 2

Carcinogenicity 1A: Carcinogenicity – Category 1A

- *** Data compared to the previous version altered.**

USA